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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY, DOCKET NO.	CONFIRMATION NO.
10/036,916	12/21/2001	Leonid Beigelman	MBHB00,00-883-K;RPI No.90	5150

20306 7590 09/26/2003

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EXAMINER

RAYMOND, RICHARD L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/036,916

Applicant(s)

BEIGELMAN ET AL.

Examiner

Richard L. Raymond

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings filed December 21, 2001 have been accepted as formal drawings by the examiner.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 and 8, drawn to diamides (formula II), classified in class 564, subclass 159.
  - II. Claims 2, 9 and 10, drawn to guanidines (formula III), classified in class 564, subclass 240.
  - III. Claims 3 and 19-21, drawn to amides (formula IV), classified in class 564, subclass 197.
  - IV. Claims 4, 30 and 31, drawn to cationic lipids (formula V), classified in class 536, subclass 29.1.
  - V. Claim 5, drawn to cationic lipids (formula VI), classified in class 564, subclass 159.
  - VI. Claims 6 and 12-18, drawn to cholesterol compounds (formula VII), classified in class 552, subclass 544.
  - VII. Claims 7, 11, 22 and 23, drawn to cholesterol compounds (formula VIII), classified in class 522, subclass 544.

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VIII. Claims 28 and 29, drawn to cationic lipids (formula IX), classified in class 564, subclass 159.

3. Claims 24-26, 32 and 33 have not been grouped as being linking claims (dependent on claims 1-7) and will be examined with the corresponding elected group.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VIII are structurally diverse and patentably distinct one from the others.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Claims 1-7 and 28 are generic to a plurality of disclosed patentably distinct species comprising the compounds of the working examples. **Whichever group is elected, applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.**

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

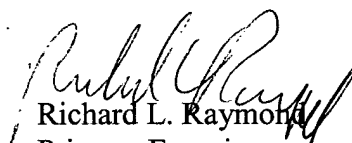
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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the 1.48(b) and by the fee required under 37 CFR 1.17(i).application. Any amendment of inventorship must be accompanied by a request under 37 CFR

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard L. Raymond whose telephone number is (703) 308-4523. The examiner can normally be reached on Monday-Thursday (9:30AM-8:00PM)).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 305-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Richard L. Raymond  
Primary Examiner  
Art Unit 1624

IT  
September 25, 2003